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3796 '02 MAR 14 P1:37

March 13, 2002

Dockets Management Branch
Food and Drug Administration, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: Docket No. 02D-0049; Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees, 67 Federal Resister, No. 29, p. 6545 (February 12, 2002)

Dear Sir or Madam:

Bristol-Myers Squibb is a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, consumer medicines, nutritionals and medical devices. We are a leader in the research and development of innovative therapies for cardiovascular, metabolic and infectious diseases, neurological disorders, and oncology. In 2001, Bristol-Myers Squibb dedicated $2.1 billion for pharmaceutical research and development activities. The company has nearly more than 6,000 scientist and physicians are committed to discover and develop best in class therapeutic and preventive agents that extend and enhance human life. Our current pipeline comprises more than 50 compounds under active development.

For these reasons, we are very interested in and well qualified to comment on this FDA proposal to ensure proper public disclosure on the nature and magnitude of a conflict of interest, particularly when FDA grants waivers to special government employees (SGEs) for product related advisory committee meetings. Bristol-Myers Squibb is commenting on this guidance as we believe that the conflicts of interest giving rise to the waivers should be clear to the public and to the sponsor whose product will be under advisement.

<u>Summary of BMS Comments on Proposal</u>

We commend the U.S. FDA for proactively seeking to increase the transparency concerning waiver procedures and the basis for decision making when waivers are granted. We appreciate the difficulty in obtaining scientific expertise from a relatively small scientific community and thereby making waivers necessary in order to provide the agency with expert opinion. We are encouraged that the FDA's survey of all advisory committee members indicated a willingness to disclose financial interest as provided in this guidance.

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However, Bristol-Myers Squibb believes that there are some aspects of the proposed guidance that could be strengthened in order to facilitate the FDA's stated objective in ensuring transparency in granting of waivers.

Section V. Substance of the Guidance

The guidance states: "**The disclosure will identify whether the interest is related to the sponsor or competitor that markets a product competing with the product at issue (without naming the competitor) and whether the SGE worked on the competing product.**" We recommend that in the interest of transparency, full disclosure of the name of the competitor, the competing product, the purpose of the grants provided by and the consultant agreements with the competitor, etc., should be made known to the public when a waiver of the conflict of interest has been granted. Without information about the true nature of the potential conflict, the disclosures would not adequately enable a reasonable person to understand the nature of the conflict and the degree to which it could be expected to influence the recommendations the SGE will make.

We also recommend that sponsors presenting a product for approval that will undergo advisory committee review should be allowed to provide a list of the specific companies and products that fall into the category of direct competitors for which special government employees should have to disclose. Such a list could be provided in advance of the advisory committee meeting and could serve to ensure that competitor companies or products were not overlooked in the disclosure process.

In "Table 1. Information to be Disclosed Concerning SGE Conflicts of Interest Waivers," the time frame for all categories of interest (stock, employment, contracts and grants, etc.) is limited to a one year period. Bristol-Myers Squibb respectfully requests that you consider a time frame of at least three years. The one-year period may artificially mask the true nature of the relationships among SGEs and sponsors or their competitors. Extending the timeframe to at least three years would substantially increase the likelihood of adequate assessment of the conflicts of interest presented by the participation of certain SGEs on product advisory committees. BMS appreciates the opportunity to provide comment and respectfully requests that FDA give consideration to our recommendations. We would be pleased to provide additional pertinent information as may be requested.

Sincerely,

Laurie Smaldone

Laurie Smaldone
Senior Vice President
Global Regulatory Sciences

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